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Thailand

Sanitary/Phytosanitary/Food Safety

Additional Food Additive (ISP) Permitted

2008

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Report Highlights:

On June 6, the Thai Food and Drug Administration issued two draft notifications listing Ice Structuring Protein type III HPLC 12 as a permitted food additive. This new notification could potentially affect U.S. ice cream and ice based food exports to Thailand, valued at \$96,000 in 2007.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Bangkok [TH1]
[TH]

Thai FDA Proposes to Permit New Food Additive

On June 6, the Thai Food and Drug Administration issued two draft notifications listing Ice Structuring Protein type III HPLC 12 as a permitted food additive and also set the standard for the use of this additive in ice-cream and other ice based foods (local ice-cream) as follows:

Ice Structuring Protein (ISP), produced from genetically modified yeast

Chemical name:	Ice Structuring Protein (ISP) type III HPLC 12
Formula:	Molecular weight 7.027 kDa
Characteristic:	Light-brown liquid produced by submerged fermentation of a genetically modified strain of yeast <i>saccharomyces cerevisiae</i> and is produced under good fermentation controlling process to generate Ice Structuring Protein, produced from genetically modified yeast or Ice Structuring Protein type III HPLC 12. Subsequently, the yeast cells are separated from the broth by microfiltration. An ultrafiltration is then used to concentrate the protein.
Specification:	<ul style="list-style-type: none">- ISP type III HPLC 12 content between 4.5-8.5 g/l- pH 2.5-3.5- Ash not more than 2%- Citric acid not more than 2%
Limit of impurities:	<ul style="list-style-type: none">- Heavy metals (calculated as lead) not more than 2 mg/l
Limit of Microbiology:	<ul style="list-style-type: none">- Total microbial count not more than 3000 per gram- Coliforms not more than 10 per g- E. Coli absent in 25 g- Listeria spp absent in 25 g- Salmonella spp absent in 25 g- Bacillus cereus not more than 100 per gram- Staphylococcus aureus not more than 10 per gram- Yeast and Mold count not more than 100 per g- Modified <i>saccharomyces cerevisiae</i> not detected
Packaging and storage	: keep in tightly sealed container at -20 degree Celsius

According to the draft notification, the permissible MRL of this food additive in foods is 50 ppm.

This notification could potentially affect U.S. ice cream and ice based food exports to Thailand, valued at \$96,000 in 2007. Currently, the U.S. FDA accepts this ISP additive as Generally Recognized as Safe (GRAS) under GRAS notice no. GRN 000117 with no specified MRL level. Commercial ice creams and edible ices treated with this ISP have been sold in the US since June 2003. According to trade sources, the Thai FDA set this additive standard according to the information provided by a European company that is planning to supply this product to Thailand. Post is continuing to assess the impact on trade.

(Copy)
Notification of Food and Drug Administration
Re: Prescription of quality or standards of single food additives (No. 3)

In order to prescribe quality or standards of additional single food additives that the Thai Food and Drug Administration allows to be used in food.

By the virtue of provision clause 4(2) of the Notification of the Ministry of Public Health (No. 281) B.E. 2547 (2004) Re: Food additives dated 18 August B.E. 2547 which issued by the virtue of provisions of Section 5 and 6 (1)(2)(4)(5)(6)(7)(9) and (10) of the Food Act B.E. 2522 (1979), in which contain provisions in relation to restriction of Rights and Liberties of the Persons, in respect of which Section 29 and in conjunction with Section 33, Section 41, Section 43, and Section 45 of the Constitution of the Kingdom of Thailand so permit by the virtue of provisions of law: the Food and Drug Administration according to an approval of the Food Committee in the meeting on issues the Notification as follows:

Add below paragraph to be No. (14) of Clause 2 of the Notification of Food and Drug Administration Re: Prescription of quality or standards of single food additives dated 24 June B.E. 2548 (2005)

“(14) Ice Structuring Protein, produced from genetically modified yeast

Chemical name: Ice Structuring Protein type III HPLC 12

Formula: Molecular weight 7.027 kDa

Characteristic: Light-brown liquid produced by submerged fermentation of a genetically modified strain of yeast *Saccharomyces cerevisiae* and is produced under good fermentation controlling process to generate Ice Structuring Protein, produced from genetically modified yeast or Ice Structuring Protein type III HPLC 12. Subsequently, the yeast cells are separated from the broth by microfiltration. An ultrafiltration is then used to concentrate the protein.

Specification:

- ISP type III HPLC 12 content between 4.5-8.5 g/l
- pH 2.5-3.5
- Ash not more than 2%
- Citric acid not more than 2%

Limit of impurities:

- Heavy metals (calculated as lead) not more than 2 mg/l

Limit of Microbiology:

- Total microbial count not more than 3000 per gram
- Coliforms not more than 10 per g
- E. Coli absent in 25 g

- *Listeria* spp absent in 25 g
- *Salmonella* spp absent in 25 g
- *Bacillus cereus* not more than 100 per gram
- *Staphylococcus aureus* not more than 10 per gram
- Yeast and Mould count not more than 100 per g
- Modified *Saccharomyces cerevisiae* not detected

Packaging and storage: keep in tightly sealed container at -20 degree Celsius

Notified on

Signed

(Copy)
Notification of Food and Drug Administration
Re: Use of Food Additive (No. 3)

By the virtue of provision clause 6.2 of the Notification of the Ministry of Public Health (No. 281) B.E. 2547 (2004) Re: Food additives dated 18 August B.E. 2547 which issued by the virtue of provisions of Section 5 and 6 (1)(2)(4)(5)(6)(7)(9) and (10) of the Food Act B.E. 2522 (1979), in which contain provisions in relation to restriction of Rights and Liberties of the Persons, in respect of which Section 29 and in conjunction with Section 33, Section 41, Section 43, and Section 45 of the Constitution of the Kingdom of Thailand so permit by the virtue of provisions of law: the Food and Drug Administration according to an approval of the Food Committee in the meeting on issues the Notification as follows:

Add below enclosed table of this notification to be a part of enclosed table of the Notification of Food and Drug Administration Re: Use of Food Additive date 3 November B.E. 2547 (2004).

Notified on

Signed

Food Additive Table**Enclosed to the Notification of Food and Drug Administration Re: Use of Food Additive**

No.	Name and Functional Class	Food Category	Max Level (Mg/1 Kg) Except already specified exact usage level.
298	Ice Structuring Protein produced from genetically modified yeast Other name: - Ice Structuring Protein type III HPLC 12 - ISP type III HPLC 12 Functional Class: - Texturizer	Ice-cream	50
		Ice based foods	50